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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,026	07/03/2000	Todd M. Boyce	285-118	3202

7590

06/13/2002

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

DATE MAILED: 06/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/610,026	Applicant(s) BOYCE ET AL.	
	Examiner Brian E Pellegrino	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 33-35 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 33-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 3-7, 10-13, 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al. (5707962). Chen et al. disclose the use of bone particles to make a sheet or membrane, col. 4, lines 44-47. Chen also discloses the source of materials can be allogenic or xenogenic and fillers can be added to the composition, col. 3, lines 4-6, 14-21. The bone particles can be demineralized, col. 4, lines 31-35. The collagen fleece (col. 7, lines 29-34) can be interpreted to contain fiber-like particles according to the definition of a fleece (a fabric or membrane of fibrous material). Also, it should be noted that since not all the particles are going to be "perfect" spheres, it is evident that there will be elongate particles present in the sheet. Chen also discloses the implant can have a "zone of impermeability" since the membrane or sheet is crosslinked, col. 8, lines 5-9 and acts as a barrier, col. 9, lines 4-6. The examiner asserts that the claimed physical properties (in this case a *void volume*) is present in the prior art material to some extent even though they are not explicitly recited. Chen does disclose a void volume (col. 5, lines 4-6), but does not explicitly recite a percentage. Therefore, the examiner hereby **burdens the applicant to show that these properties (not greater than 32%) are not present in the prior art.** *It is also noted that the void volume range does include 0%.*

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. '962. Chen is explained supra. However, Chen does not disclose a thickness of about 50-2000 microns and to mechanically shape the coherent mass of bone particles or composition to a specific 3-D architecture. Chen teaches that the implant can be used in various procedures, i.e. periodontal bone grafting (col. 6, lines 16-22). It would have been obvious to one of ordinary skill in the art to mechanically shape the implant into a 3-D component such that it would meet the individual's required physical specifications. It would have been obvious to one of ordinary skill in the art to vary the implant thickness to be about 50-2000 microns, since applicant has not disclosed the thickness dimensions as an important feature or solves any stated problem or is for any particular purpose and it appears the thickness of Chen serves equally well.

Chen discloses the bone particles are demineralized at 90%, col. 7, line 39. However, Chen does not disclose bone particles that are fully demineralized (<8% mineral content). It would have been obvious to one of ordinary skill in the art to modify the composition of Chen et al. and fully demineralize the composition since applicant has not disclosed that fully demineralizing the bone particles as an important feature or solves any stated problem or is done for any

particular purpose and it appears the implant would serve the same function with the partially demineralized bone particles.

Response to Arguments

Applicant's arguments filed 3/27/02 have been fully considered but they are not persuasive. In response to Applicant's argument that Chen does not inherently use "elongate" particles or has a void volume not greater than about 32%, it has been held that a claim is anticipated if each element of the claims is found, either expressly described or under principles of inherency, in a single prior art reference, or that the claimed invention was previously known or embodied in a single prior art device or practice. *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 789. In this case, the Chen reference does disclose "elongate" particles. It should be noted that claims in a pending application are to be given their broadest reasonable interpretation. In re Hyatt, 54 USPQ 1664 (Fed. Cir. 2000). Therefore, a fleece of fiber-like particles can be interpreted to include "elongate" particles because not all the particles are going to be "perfect" spheres.

Secondly, the claims do not require that the composition have a void volume because applicant's range includes 0%. Additionally, applicant has not shown that Chen's void volume (col. 5, lines 4-6) is greater than 32%. Because the Patent and Trademark Office does not have the testing facilities to provide factual evidence needed to establish that the claimed subject matter is not anticipated or unobvious, the examiner properly shifts the burden to applicants to

show unanticipated or unobvious differences exist, Ex parte Phillips, 28 USPQ 1302 (Bd Pat App & Inter, 4/27/93).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Interviews After Final

Applicant note that an interview after a final rejection will not be granted unless the intended purpose and content of the interview is presented briefly, in writing (the agenda of the interview must be in writing). Such an interview may be granted if the examiner is convinced that disposal or clarification for appeal may be accomplished with only nominal further consideration. Interviews merely to restate arguments of record or to discuss new limitations which would require

more than nominal reconsideration or new search will be denied. See MPEP 714.13 and 713.09.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (703) 306-5899. The examiner can normally be reached on Monday-Thursday from 8:30am to 6pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-2708.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Brian E. Pellegrino

TC 3700, AU 3738
June 11, 2002

A handwritten signature in black ink, appearing to read "Paul Prebilo", with a long horizontal flourish extending to the right.

Paul Prebilo

Primary Examiner